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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,034	10/03/2006	Fraser W. Scott	034205.003 (08899427US1)	5076
61690	7590	11/19/2010	EXAMINER	
SUZANNAH K. SUNDBY			EWOLDT, GERALD R	
SMITH, GAMBRELL & RUSSEL, LLP				
1130 Connecticut Avenue, NW			ART UNIT	PAPER NUMBER
Suite 1130				1644
WASHINGTON, DC 20036				
			NOTIFICATION DATE	DELIVERY MODE
			11/19/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/597,034	SCOTT ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 August 2010 and 15 September 2010.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-5,21,24,25 and 36 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,3-5,21,24,25 and 36 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/18/10</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

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DETAILED ACTION

1. Applicant's IDS, filed 8/18/10, and amendment, remarks, and Sequence Listing, filed 9/15/10, are acknowledged.

2. Claims 1, and 3-5 were previously under examination. Examination has been extended to include Claims 21, 24, and 25. New Claim 36 has been added.

3. In view of Applicant's amendment the previous rejection under the first paragraph of 35 U.S.C. 112 has been withdrawn.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 4 stand rejected under 35 U.S.C. 102(b) as being anticipated by MacFarlane et al. (2003, IDS).

As set forth previously, MacFarlane et al. teaches a Glb1 isoform, the protein expressed from clone WP5212, comprising the EEQLRELRRQ amino acid sequence of SEQ ID NO:1 (see particularly, EXPERIMENTAL PROCEDURES, page 55, wherein the protein is expressed). The reference further teaches the protein attached to a support (see particularly *One and Two-Dimensional Western Blotting*, page 57, wherein the peptide is attached to nitrocellulose).

Applicant's arguments, filed 9/15/10, have been fully considered but are not found persuasive. Applicant argues that reference does not disclose the peptide of SEQ ID NO:1.

The reference is authored by three of the instant inventors. The reference teaches a clone with the same name from the same source as that disclosed in the specification. Absent any reasonable explanation as to why the authors/inventors would use the same name for a clone from the same source, the clone of the reference must be considered to be the clone of the instant application and claims.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 3 stands rejected under 35 U.S.C. 103(a) as being unpatentable over MacFarlane et al. (2003, IDS) in view of U.S. Patent No. 6,803,221.

As set forth previously, MacFarlane et al. has been discussed above.

The reference teaching differs from the claimed invention in that it does not teach the diabetogenic epitope of Glb1 further comprising a protein or peptide that does not occur in nature.

The '221 patent teaches that proteins or peptides of interest are routinely attached to other proteins or peptides for numerous reasons (see the entire document). Specifically, proteins or peptides are routinely attached to histidine hexamers (which would not be considered to be naturally occurring) to facilitate the purification of the protein or peptide (see particularly, column 14, lines 50-61).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to fuse the histidine hexamer of the '221 patent to the Glb1 protein of MacFarlane et al. to facilitate the purification of the recombinant protein such that it might be used in the autoantibody assays of MacFarlane et al..

Applicant argues the deficiency of the primary reference.

See the examiner's response in part 5 above.

8. Claims 4 and 5 stand rejected under 35 U.S.C. 103(a) as being unpatentable over MacFarlane et al. (2003, IDS) in view of U.S. Patent No. 6,927,041.

As set forth previously, MacFarlane et al. has been discussed above.

The reference teaching differs from the claimed invention in that it does not teach the diabetogenic epitope of Glb1 attached to a support such as a bead, a plate, or a slide.

The '041 patent teaches that proteins or peptides of interest are routinely attached to a bead, a plate, or a slide to facilitate separation and to accommodate assays (see particularly column 22, line 60 - column 23, line 15).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to attach the Glb1 protein of MacFarlane et al. to the bead, plate, or slide of the '221 patent to the Glb1 protein of

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MacFarlane et al. to facilitate separation and to accommodate assays.

Applicant argues the deficiency of the primary reference.

See the examiner's response in part 5 above.

9. The following are new grounds for rejection.

10. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claim 1, 21, and 36 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the compositions of the claims are products of nature, i.e., the unisolated amino acid sequences of SEQ ID NO:1 and SEQ ID NO:4. NOTE: the recitation of "An isolated amino acid sequence..." would obviate the rejection.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- e) the invention was described in--
 - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
 - (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

13. Claims 1, 3-5, and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 7,214,786.

The '786 patent teaches the amino acid sequences of SEQ ID NO:1 (SEQ ID NO:211,164 in the '786 patent) and SEQ ID NO:4 (SEQ ID NO:118,877 in the '786 patent). The reference further teaches peptides with conservative substitutions, i.e., a

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substituted protein of SEQ ID NO:118,877 in the '786 patent would comprise a peptide of SEQ ID NO:1 that does not occur normally in nature (see particularly column 9, lines 37-40). The reference further teaches antibody probes specific for the peptides and proteins of the reference (see particularly column 10, line 25) as well as ELISAs (see particularly column 14, line 22) and arrays (see particularly column 16, lines 19-32), both of which would inherently comprise plates and supports.

The reference clearly anticipates the claimed invention.

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 21, 24, and 25 are rejected under 35 U.S.C. 103(a) each as being unpatentable over U.S. Patent No. 7,214,786 in view of U.S. Patent No. 4,281,061.

The '786 patent has been discussed above.

The reference differs from the claimed invention only in that it does not teach the claimed reagents in a kit form.

The '061 patent teaches that reagents can be provided in kits as a matter of convenience and for the optimization of their use (see particularly column 22, line 62 - column 23, line 4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide the reagents of the '786 patent in the kit form of the '061 patent. One of ordinary skill in the art would have been motivated to provide said kit given the teachings of the '061 patent that reagents can be provided in kits as a matter of convenience and for the optimization of their use.

16. No claim is allowed.

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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0841.

18. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

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